Stratton VA Medical Center IRB Standard Operating Procedure

TITLE: **Initial Review of Research**			DOCUMENT NUMBER: **IRB-001**
REVISION NO.: 01	SUPERSEDES/DATE: 00/10-8-03	EFFECTIVE DATE: May 14, 2004	PAGE 1 OF 7

IRB CHAIR OR DESIGNEE:	ACOS R&D:	COMPLIANCE:
Signature	Signature	Signature
Name	Name	Name
5/12/04	Donald R Sousa Jr	LESA PAULSEN-CORTES
Date	Date	Date
7 Steven	May-13-04	5-14-04

1 POLICY

It is Stratton VA Medical Center's policy to comply with all applicable local, state, and federal regulations, and ICH guidelines in the conduct of clinical research studies. Written procedures are required for documenting expedited and full committee review of new protocols, and for reporting the IRB's actions to the Principal Investigator.

2 DEFINITIONS

Institutional Review Board (IRB): The Stratton VA Medical Center Institutional Review Board, formally designated by Stratton VA Medical Center to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects.

IRB Chair designee: An IRB member with one or more years of experience on the IRB.

IRB Staff: Members of the Research Office who support the functions of the IRB.

Principal Investigator(s): Individual(s) who actually conducts a research investigation under whose immediate direction research is conducted, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.

3 FORMS

New Protocol Submission Form
Primary Reviewer Form
Conditions of IRB Approval
Report of Subcommittee on Human Studies (VA Form 10-1223)
New Protocol Submission Checklist
Notification of Disapproval letter
HIPAA Authorization
Waiver of HIPAA Authorization

4 REFERENCE DOCUMENTS

45 CFR 46
21 CFR 50, 56
38 CFR 16
VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research
ICH Harmonised Tripartite Guideline For Good Clinical Practice (1 May 1996)

5 PROCEDURE

5.1 Principal Investigators will request review of research by submitting a New Protocol Submission Form, with copies of all supporting documents.

5.2 The IRB Staff checks the investigator education training list to assure the Principal Investigator(s), co-investigators, and sub-investigators are certified and credentialed to submit new research.

5.2.1 If they are not certified and credentialed, the IRB staff will inform the PI of the requirements. Final approval of the research will be contingent upon completion of the educational training requirements for all research staff listed on the New Protocol Submission Form.

5.3 The IRB staff checks the original submission for completeness and accuracy and enters the submission into the database. For example:

5.3.1 Verify that the New Protocol Submission Form has the signatures of the PI(s), all co-investigators, sub-investigators, and Care Line Leader(s).

5.3.1.1 The signature of the Principal Investigator(s) ensures that all changes in previously approved protocols will be reported to the IRB. Proposed changes will not be implemented without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.

5.3.2 Verify that if Investigational New Drug(s) (IND) or Investigational Device Exemptions (IDE) will be used, an IND# or IDE# is listed on the New Protocol Submission Form. If an IND# or IDE# is not listed, the IRB staff will not accept the submission from the Principal Investigator(s) or designated contact person until the information is complete.

5.3.3 Verify that an appropriate number of copies of attachments are included according to the New Protocol Submission Checklist.

5.4 If any items are missing, the IRB staff will notify the Principal Investigator(s) or the designated contact person.

5.5 Research that represents no more than minimal risk and falls into one or more categories listed in "Categories of Research That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure" may be reviewed by expedited review or by the full IRB. All other research must be reviewed by the full IRB.

5.5.1 The HRPP Coordinator consults with the IRB Chair or designee to discuss whether the research will be processed by full committee review or by expedited review.

5.6 Expedited Review Process:

5.6.1 A member of the IRB staff pre-reviews the research. The IRB Chair or designee conducts the review.

5.6.2 The IRB Chair or designee conducting expedited review has the final authority in deciding whether the research qualifies for expedited review and may recommend full committee review.

5.6.3 In order to approve research covered by this policy the reviewer shall determine that the research:

5.6.3.1 Represents no more than minimal risk.

5.6.3.2 Falls into one or more "Categories of Research That May be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure".

5.6.3.3 Satisfies the criteria for approval of research (38 CFR 16.111).

5.6.4 If the reviewer requests changes or additional information, the IRB staff contacts the Principal Investigator(s)or the designated contact person and requests the information. Upon receipt of the requested information, the changes or additional information are forwarded to the reviewer.

5.6.5 If the reviewer still cannot approve the research as submitted, the Principal Investigator(s) or designated contact person is notified. The Principal Investigator(s) may modify the research for resubmission to the IRB or resubmit the research for review at a full IRB meeting.

5.6.6 If the reviewer recommends full committee review, the Principal Investigator(s) or designated contact person is notified that the research must be reviewed by the full committee and is asked to provide additional copies of the research submission.

5.6.7 The reviewer may not disapprove new research under Expedited Review.

5.6.8 If the reviewer finds the research acceptable:

5.6.8.1 The IRB Chair or designee who reviewed the research approves the research.

5.6.8.2 The IRB Chair or designee signs and dates the IRB Approval – Initial Review letter, indicating the risk level and the interval of approval.

5.6.8.3 The IRB Approval – Initial Review letter, and approved stamped consent(s) are sent to the Principal Investigator(s).

5.6.8.4 The IRB is notified of the approval in the agenda of the next scheduled IRB meeting.

5.6.8.5 New research approved by Expedited Review receives an interval of approval of no more than 365 days.

5.7 Full Committee Review:

5.7.1 Research that requires full committee review is placed on the agenda of the monthly IRB meeting and is distributed approximately two weeks in advance of the meeting. The agenda identifies all IRB members who are also participating in the research to alert the committee of a conflict of interest.

5.7.2 The IRB staff assigns two primary reviewers, who are not participating in the research, based on their area of expertise.

5.7.3 Primary reviewers are given a copy of the New Protocol Submission Form and the entire research submission, including the protocol, abstract, consent document(s), investigator brochure(s), advertisements, participant materials, Financial Conflict of Interest disclosure forms, HIPAA authorization and/or waiver request, and applicable research grants or budget copies approximately two weeks in advance of the meeting.

5.7.3.1 Primary reviewers are provided with a Primary Reviewer Form to record their comments.

5.7.3.2 Committee members who are not primary reviewers are given a copy of the New Protocol Submission Form, the protocol, consent documents, advertising, HIPAA authorization and/or waiver request, and participant materials approximately two weeks in advance of the meeting.

5.7.4 The review of research takes place at the monthly meeting of the IRB.

5.7.5 In order to approve a new research protocol, the IRB shall determine that criteria for approval of research are satisfied (38 CFR 16.111).

5.7.6 The IRB staff takes minutes at the meeting pertaining to discussion of the research and any controverted issues and their resolution.

5.7.7 Minutes are prepared within one week after the meeting and include:

5.7.7.1 Attendance of IRB members at the meeting.

5.7.7.2 The votes for, against, abstaining, recused, and excused,as well as the recommended period of approval. IRB members with a conflicting interest must recuse themselves from voting.

5.7.7.3 Modifications or any other changes to the research required by the IRB.

5.7.7.4 The basis for requiring changes in or disapproving research.

5.7.7.5 A written summary of any discussion of controverted issues and their resolution.

5.7.7.6 Documentation of required IRB findings such as:

5.7.7.6.1 Alteration or waiver of requirements for informed consent

5.7.7.6.2 Waiver of requirement to obtain signed consent

5.7.7.6.3 Research involving vulnerable participants

5.7.8 If the research is approved as submitted:

5.7.8.1 The IRB Chair or designee signs and dates the IRB Approval – Initial Review letter.

5.7.8.1.1 The Date of Approval is the date of the meeting at which the research was approved.

5.7.9 If the research is granted approval with modifications:

5.7.9.1 The modifications must be documented in sufficient detail to allow the IRB staff to verify the changes required by the IRB.

5.7.9.2 A Notification of Approval with Contingencies letter, listing all required modifications and conditions for approval, is sent to the Principal Investigator(s).

5.7.9.3 The Principal Investigator(s) responds to the Research Office with a copy of all modified documents within 3 months.

5.7.9.4 The IRB staff reviews the modified documents for confirmation of all modifications required by the IRB.

5.7.9.5 If the submitted documents have not been modified as required, the Principal Investigator(s) is contacted by IRB staff and asked to submit the complete revision as requested.

5.7.9.6 Once the IRB staff determines that the documents contain all required modifications, the IRB Chair or designee signs the IRB Approval – Initial Review letter.

5.7.9.6.1 The Date of Approval is the date of the meeting at which the research was approved with modifications.

5.7.9.7 If the Principal Investigator(s) does not return the required modified documents within approximately three months, as indicated on the Contingent Approval letter,

the IRB Chair or designee notifies the Principal Investigator(s) in writing that the protocol remains unapproved and further consideration of this research will require submission of a new protocol.

5.7.10 If the research is disapproved, the IRB Chair or designee notifies the Principal Investigator(s) in the Notification of Disapproval letter of the reasons for disapproval and offers the Principal Investigator(s) an opportunity to resubmit the research to the IRB within three months.

5.7.10.1 If the Principal Investigator(s) resubmits the research to the IRB, the disapproval letter will be distributed with the agenda and included in the primary reviewer materials for the next scheduled IRB meeting.

5.8 The IRB may require proposed research to be reviewed and approved by the VAMC Radiation Safety Committee, Subcommittee on Research Safety & Biosafety (SRS&B), Institutional Animal Care and Use Subcommittee (IACUC), other committees of the VAMC, relevant committees of collaborating institutions, or by ad hoc reviewers.

5.9 Informed consent forms and HIPAA authorizations associated with approved research are stamped with a Date of Approval and a Date of Expiration. A copy of the stamped consent(s), HIPAA authorizations, and approval letter will be provided to the investigator.

5.9.1 The Date of Approval is defined as the date of the meeting at which the research was approved.

5.9.2 The Date of Expiration is defined as the Date of Approval plus the recommended interval of review.

5.10 The research protocol and copies of documents received and sent are filed in the Research Office.

5.11 The IRB staff files the Primary Reviewer Form with the research submission.